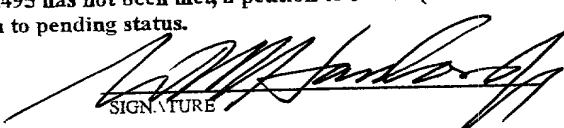


FORM PTO-1390 (REV. 11-2000)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTORNEY'S DOCKET NUMBER DFS-129-A
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371			U.S. APPLICATION NO. (If known, see 37 CFR 1.5) Unknown 09/937644
INTERNATIONAL APPLICATION NO. PCT/EP00/01824	INTERNATIONAL FILING DATE 03 March 2000	PRIORITY DATE CLAIMED 27 March 1999	
TITLE OF INVENTION SINGLE-UAW HYGIENE ITEMS			
APPLICANT(S) FOR DO/EO/US Andreas Bitterhof			
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:			
<ol style="list-style-type: none"> 1. <input checked="" type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 U.S.C. 371. 2. <input type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371. 3. <input checked="" type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. 4. <input checked="" type="checkbox"/> The US has been elected by the expiration of 19 months from the priority date (Article 31). 5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)) <ol style="list-style-type: none"> a. <input checked="" type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> has been communicated by the International Bureau. c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US). 6. <input checked="" type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). <ol style="list-style-type: none"> a. <input checked="" type="checkbox"/> is attached hereto. b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4). 7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) <ol style="list-style-type: none"> a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> have been communicated by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input type="checkbox"/> have not been made and will not be made. 8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)). 9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). 10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). 			
Items 11 to 20 below concern document(s) or information included:			
<ol style="list-style-type: none"> 11. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12. <input checked="" type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. <input checked="" type="checkbox"/> A FIRST preliminary amendment. 14. <input type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment. 15. <input checked="" type="checkbox"/> A substitute specification. 16. <input type="checkbox"/> A change of power of attorney and/or address letter. 17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825. 18. <input type="checkbox"/> A second copy of the published international application under 35 U.S.C. 154(d)(4). 19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4). 20. <input checked="" type="checkbox"/> Other items or information: Red-Lined Specification 			

U.S. APPLICATION NO. (if known) 37 CFR 1.53 U099/937644		INTERNATIONAL APPLICATION NO. PCT/EP00/01824		ATTORNEY'S DOCKET NUMBER DFS-129-A	
21. <input checked="" type="checkbox"/> The following fees are submitted: BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)): Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO..... \$1000.00 International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO \$860.00 International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO \$710.00 International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) \$690.00 International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) \$100.00 ENTER APPROPRIATE BASIC FEE AMOUNT =				CALCULATIONS PTO USE ONLY	
				\$ 860	
				\$ 0	
				\$	
				\$	
Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				\$	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	15 - 20 =		x \$18.00		
Independent claims	2 - 3 =		x \$80.00		
MULTIPLE DEPENDENT CLAIM(S) (if applicable)				+ \$270.00	
TOTAL OF ABOVE CALCULATIONS =				\$ 860	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.				\$ 0	
SUBTOTAL =				\$ 860	
Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				\$ 0	
TOTAL NATIONAL FEE =				\$ 860	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +				\$ 40	
TOTAL FEES ENCLOSED =				\$ 900	
				Amount to be refunded:	\$
				charged:	\$
a. <input checked="" type="checkbox"/> A check in the amount of \$ <u>900.00</u> to cover the above fees is enclosed. b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed. c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>25-0115</u> . A duplicate copy of this sheet is enclosed. d. <input type="checkbox"/> Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.					
NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the application to pending status.					
SEND ALL CORRESPONDENCE TO William M. Hanlon, Jr. YOUNG & BASILE, PC 3001 West Big Beaver Road Suite 624 Troy, Michigan 48084 248-649-3333					
				 SIGNATURE William M. Hanlon, Jr. NAME 28422 REGISTRATION NUMBER	

T02060-4492660

09/937644

JC09 Rec'd PCT/PTO 27 SEP 2001
PATENT

Our Reference: DFS-129-A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Andreas Bitterhof
Serial Number: Unknown
Filing Date: Concurrent
Examiner/Art Group Unit: Unknown/Unknown
Title: SINGLE-USE HYGIENE ITEMS

PRELIMINARY AMENDMENT

Assistant Commissioner of Patents
Washington, D.C. 20231

Sir:

Prior to initial examination, please amend the above-identified patent application as indicated below.

In the specification:

Between paragraphs 0017 and 0018, please insert the following new paragraph:

BRIEF DESCRIPTION OF THE DRAWING

- [0017.1] In the drawing:
- [0017.2] Fig. 1 is a plan view of one aspect of an insert for a hygiene item according to the present invention;
- [0017.3] Fig. 2 is a bottom view of the insert of Fig. 1;
- [0017.4] Fig. 3 is a longitudinal cross-section view of the insert of Fig. 1; and
- [0017.5] Fig. 4 is a longitudinal cross-section view of another aspect of the insert of the present invention.

After the claims, start a new page and insert--

ABSTRACT

[0026] A single-use hygiene item includes an insert in the form of an absorbing body that absorbs and holds body fluids and an analysis device for the body fluid which is provided at a location where the body fluid to be analyzed can be impinged upon. The analysis device is separated from the absorbing body in an essentially a liquid-proof manner or, optionally, by means of a separating layer in such a way that the body fluid to be analyzed can directly reach the analysis device.

In the claims:

1 1. (Amended) A single-use hygiene item having an absorbent
2 element for absorbing and retaining bodily fluid and having an analysis device for the
3 bodily fluid, characterized in that the analysis device is disposed at an area of the
4 hygiene item on which the bodily fluid to be analyzed can impinge and is separated in
5 an essentially fluid-tight manner from the absorbent element by a separating means,
6 so that bodily fluid passed by a user to be analyzed can reach the analysis device
7 directly, but bodily fluid that has penetrated to the absorbent element is retained by
8 the separating means away from the analysis device.

1 2. (Amended) The hygiene item in accordance with claim 1,
2 wherein the separating medium forms an insert in the absorbent element containing
3 the analysis device.

1 3. (Amended) The hygiene item in accordance with claim 2,
2 wherein the insert is dish-shaped.

1 4. (Amended) The hygiene item in accordance with claim 2,
2 wherein the insert has sidewalls extending up on a side facing the body.

1 5. (Amended) The hygiene item in accordance with claim 2,
2 wherein edges of the insert are folded over on an upper side.

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1 6. (Amended) The hygiene item in accordance with claim 2,
2 wherein the insert is delineated by a fluid-impermeable film.

1 7. (Amended) The hygiene item in accordance with claim 2
2 wherein the insert is located essentially flush-mounted with the upper side of the
3 absorbent element facing the body.

1 8. (Amended) The hygiene item in accordance with claim 2,
2 wherein the analysis device is positioned up against one side of the separating means.

1 9. (Amended) The hygiene item in accordance with claim 2,
2 wherein the analysis device has a visual display unit.

1 10. (Amended) The hygiene item in accordance with claim 8,
2 wherein a side of the separating means against which the analysis device is disposed,
3 is made transparent, at least in the area of the analysis device, so that a visual reading
4 of the display unit is possible.

1 11. (Amended) The hygiene item in accordance with claim 2,
2 wherein the separating means containing the analysis device is separable from the
3 hygiene item.

1 12. (Amended) The hygiene item in accordance with claim 2,
2 wherein the separating means containing the analysis device is detachably fastened to
3 the hygiene item by means of one of an adhesive and a touch-sensitive means of
4 attachment.

1 13. (Amended) The hygiene item in accordance with claim 2,
2 wherein the insert containing the analysis device has a fluid absorbing and transport
3 layer which transfers the bodily fluid to the analysis device.

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1 14. (Amended) The hygiene item in accordance with claim 13,
2 wherein the fluid absorbing and transport layer comprises cellulose fibers without the
3 addition of superabsorbent polymer materials.

1 15. (Amended) An analysis device for measuring the composition
2 of bodily fluids, in a single-use hygiene item having an absorbent element to absorb
3 and retain bodily fluids.

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REMARKS

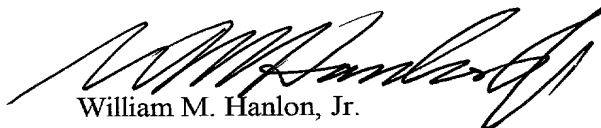
After entry of this amendment, claims 1-15 have been amended.

A handwritten, corrected copy of the specification is enclosed showing the changes which have been made to the specification as required by Section 608.01 (Q) and 714.20 (1) of the Manual of Patent Examining Procedure. The Substitute Specification filed herewith has been amended to utilize idiomatic English, correct United States patent practice. The Substitute Specification includes no new subject matter; but does include the same changes handwritten in red in the attached, corrected, original specification. Entry of the Substitute Specification is respectfully requested.

It is submitted that this Amendment has antecedent basis in the application as originally filed, including the specification, claims and drawings, and that this Amendment does not add any new subject matter to the application. Consideration of the application as amended is requested.

Respectfully submitted,

YOUNG, BASILE, HANLON, MacFARLANE, WOOD
& HELMHOLDT, P.C.



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Dated: September 27, 2001
WMH/jao

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

1 1. (Amended) [Single-use] A single use hygiene item[, such as a
2 diaper, incontinence article, sanitary napkin,] having an absorbent element for
3 absorbing and retaining bodily fluid and having an analysis device for the bodily
4 fluid, characterized in that the analysis device [(4)] is disposed at an area of the
5 hygiene item on which the bodily fluid to be analyzed can impinge and is separated in
6 an essentially fluid-tight manner from the absorbent element by a separating means
7 [(8)], so that bodily fluid passed by a user to be analyzed can reach the analysis
8 device [(4)] directly, but bodily fluid that has penetrated to the absorbent element is
9 retained by the separating means [(8)] [and kept] away from the analysis device (4).

1 2. (Amended) [Hygiene] The hygiene item in accordance with
2 claim 1, wherein the separating medium [(8)] forms an insert [(2)] in the absorbent
3 element containing the analysis device [(4)].

1 3. (Amended) [Hygiene] The hygiene item in accordance with
2 claim 2, wherein the insert [(2)] is dish-shaped.

1 4. (Amended) [Hygiene] The hygiene item in accordance with
2 claim 2 [or 3], wherein the insert [(2)] has sidewalls [(10)] extending up on [the] a
3 side facing the body.

1 5. (Amended) [Hygiene] The hygiene item in accordance with
2 [one of the preceding claims] claim 2 [to 4], wherein edges [(12)] of the insert [(2)]
3 are folded over on [their] an upper side [(14)].

1 6. (Amended) [Hygiene] The hygiene item in accordance with
2 [one of the preceding claims] claim 2 [to 5], wherein the insert [(2)] is delineated by
3 a fluid-impermeable film [(6)].

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1 7. (Amended) [Hygiene] The hygiene item in accordance with
2 [one of the preceding claims] claim 2, wherein the insert [92]) is located essentially
3 flush-mounted with the upper side [(14)] of the absorbent element facing the body.

1 8. (Amended) [Hygiene] The hygiene item in accordance with
2 [one of the preceding claims], claim 2 wherein the analysis device [(4)] is positioned
3 up against one side [(20)] of the separating means [(8)].

1 9. (Amended) [Hygiene] The hygiene item in accordance with
2 [one of the preceding claims], claim 2 wherein the analysis device [(4)] has a visual
3 display unit.

1 10. (Amended) [Hygiene] The hygiene item in accordance with
2 claim 8 [or 9], wherein [the] a side [(20)] of the separating means [(8)] against which
3 the analysis device is [lying], disposed is made transparent, at least in the area of the
4 analysis device (4), so that a visual reading of the display unit is possible.

1 11. (Amended) [Hygiene] The hygiene item in accordance with
2 [one of the preceding claims], claim 2 wherein the separating means [(8)] containing
3 the analysis device is separable from the hygiene item.

1 12. (Amended) [Hygiene] The hygiene item in accordance with
2 [one of the preceding claims], claim 2 wherein the separating means [(8)] containing
3 the analysis device [(4)] is detachably fastened [detachably] to the hygiene item by
4 means of one of an adhesive [or] and a touch-sensitive means of attachment [(28)].

1 13. (Amended) [Hygiene] The hygiene item in accordance with
2 [one of the preceding claims], claim 2 wherein the insert [(2)] containing the analysis
3 device has a fluid absorbing and transport layer [(18)] which transfers the bodily fluid
4 to the analysis device.

1 14. (Amended) [Hygiene] The hygiene item in accordance with
2 claim 13, wherein the fluid absorbing and transport layer [(18)] comprises cellulose
3 fibers without the addition of superabsorbent polymer materials.

1 15. (Amended) [Use of an] An analysis device for measuring the
2 composition of bodily fluids[, specifically for measuring pH, nitrite, leukocyte,
3 glucose and/or electrolyte values of urine or blood], in a single-use hygiene item
4 having an absorbent element to absorb and retain bodily fluids[, such as a diaper,
5 incontinence article or sanitary napkin].

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JC09 Rec'd PCT/PTO 27 SEP 2001

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SUBSTITUTE SPECIFICATION

Our Reference: DFS-129-A

PATENT

SINGLE-USE HYGIENE ITEMS

BACKGROUND

- [0001] The invention relates to a single-use hygiene item, such as a diaper, an incontinence article or a sanitary napkin, having an absorbent element for absorbing and retaining bodily fluids and having an analysis device for the bodily fluid.
- [0002] Hygiene items are known which have indicator strips which undergo a change in color when wetted with urine and thus indicate in a visually perceptible manner when they are saturated. Since these indicator strips, in the broadest sense, represent an analysis device for the bodily fluid, the point of departure for the present invention was a hygiene item having an analysis device.
- [0003] However, in the case of hygiene items, there is not only the necessity of monitoring their state of saturation and of indicating when the hygiene item is in a depleted condition, there is the fundamental need to analyze urine, for example, with respect to its composition. Consequently, the proposal is put forward in EP 0 438 482 B1 to provide an analysis device in a urine collection bag with indicating devices exposed to urine. Specifically, they are indicating devices which analyze the urine reaching the urine collection bag for its pH, nitrite, leukocyte, glucose and electrolyte values. The indicating devices are initially white and change color after being wetted with the urine to be analyzed. In an acidic medium, for example, a section of a pH-value indicator will turn yellow and in an alkaline medium it will turn blue. Analysis devices, identified as control cards, are described having a color chart with several colors under a particular indicator section, by means of which a user can assign the color reaction of the indicator being monitored to a value. This value is given in another line below the color chart.
- [0004] According to the teaching of this publication, each particular indicator panel on the urine-exposed side is covered by a membrane which has perforations consisting of extremely small holes. This membrane forms a type of metering device and allows the urine to reach the indicator panel only very slowly. In this way an initial flow of urine entering the empty collection bag with a high concentration of

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germs is prevented from causing a supercritical display which cannot normally be triggered by the main urine stream. In the same way, the residual urine, which differs from the main stream, also cannot determine the reading by itself. As a result of the relatively slowed down passage through the membrane, the urine to be analyzed is brought to the indicator panel "well mixed." In an advantageous further configuration of the analysis device, this publication describes that the indicator substances of the indicator field are embedded in a material which swells in the presence of moisture. In this way, as the material swells, pressure is built up against the membrane, and as a result the passage of urine is rendered even more difficult. In this way, flushing out of the color-creating indicator substances is counteracted, and an unbiased, accurate reading of the quasi-frozen display values can be taken even after many hours.

[0005] Whenever analysis devices are used, an effort is made, or a need even exists, to ensure that the substances to be analyzed come into contact in as unadulterated a form as possible with the measurement-sensitive means, that is to say, with the indicators on the analysis device, to ensure as accurate a measurement result as possible, free of any interaction.

[0006] For this reason the analysis device in accordance with the aforementioned EP 043842 B1 was also located in a urine routing system connected to a urethral catheter in the form of a urine collection bag.

[0007] This is naturally experienced as unpleasant by patients whose bodily fluid is to be subjected to analysis. In addition, it is a medically complicated procedure. In the case of incontinent persons, the possibility also does not exist of passing the bodily fluid to be analyzed into a container for purposes of analysis. Using this as the starting point, it would be desirable to expand the application of an intrinsically familiar analysis device described in EP 0 438 482 B1, specifically to render the use of a urine routing system attached to a urethral catheter unnecessary.

SUMMARY

[0008] This desire is fulfilled through the use of an analysis device in accordance with the invention for measuring the composition of the bodily fluids, specifically for measuring pH, nitrite, leukocyte, glucose and/or electrolyte values of

urine or blood, in a single-use hygiene item with an absorbent element for absorbing and retaining bodily fluids, as for example, a diaper, an incontinence article or a sanitary napkin.

[0009] As a result of the use in accordance with the invention, it becomes possible for the first time to employ analysis devices for measuring the composition of bodily fluids outside a urine routing system. With the invention, protection is therefore also provided for an intrinsically familiar hygiene item which has an analysis device for measuring the composition of the bodily fluid to be absorbed, specifically for measuring pH, nitrite, leukocyte, glucose and/or electrolyte values.

[0010] In a further development of this concept, a hygiene item of the type described at the outset is proposed, which, in accordance with the invention, is characterized in that the analysis device is disposed at a place on the hygiene item which can be impinged upon by the bodily fluid to be analyzed and is separated by means of a separating means in an essentially fluid-tight manner from the absorbent element, so that bodily fluid passed by a user to be analyzed can reach the analysis device directly, but bodily fluid passed into the absorbent element is retained by the separating means and kept away from the analysis device.

[0011] The aspect of the hygiene item according to the invention has the advantage that bodily fluid to be analyzed is not affected by interaction with absorbent element materials in the hygiene article which may be present and/or by the leaching out of substances from the absorbent element material which affect the analysis reaction, and thus falsify the result of the measurement. For example, the absorbent element of modern hygiene items normally comprises so-called superabsorbent polymer materials which retain many times their own weight in fluid. These substances, however, have a falsifying effect on the measurement of individual components. Due to the fact that the analysis device is separated by the aforementioned separating means in a basically fluid-tight manner from the absorbent element of the hygiene item, it is ensured that urine which was biased as a result of the interaction with the materials of the absorbent element with respect to the analysis reaction, does not reach the analysis device and is not analyzed there.

[0012] The separating means could, in the simplest instance, comprise an essentially fluid-impermeable layer of film. The separating means in a further development of the invention forms an insert in the hygiene item containing the analysis device and/or in the absorbent element of the hygiene item. The term "insert" is to be understood as an area of the hygiene item separated by the separating means from the remainder of the absorbent element. This insert or area can, for example, be dish-shaped and have side walls extending up on the side facing the body.

[0013] In a further aspect of the hygiene item according to the invention, edges of this insert are folded over on its top side.

[0014] The insert is advantageously delineated by a fluid-impermeable film, which simultaneously forms the separating means.

[0015] The separating means and/or the insert could be disposed as a relatively shallow elevation on the upper side of the absorbent element of the hygiene item, so that the insert is impinged upon first by the bodily fluid passed by a user of the hygiene item, which can then penetrate into the adjacent areas of the absorbent element after the insert is filled.

[0016] In a further advantageous aspect of the invention, the insert is located essentially flush over its surface with the top side of the absorbent element facing the body.

[0017] In essence, the analysis device could be disposed in any way at all, separated by the separating means from the absorbent element. In a further development of the invention, however, it is proposed that the analysis device is disposed resting against one side of the separating means. When the hygiene item is impinged upon by bodily fluid, the latter will normally travel as far as the separating means following gravity and there come into contact with the analysis device.

DETAILED DESCRIPTION

[0018] A standard, familiar hygiene item, for example, a diaper, an incontinence article or a sanitary napkin, can be made in accordance with the present invention having an analysis device to measure and check the composition of bodily fluids. Figures 1 to 3 provide an initial embodiment of an insert 2 which can be

integrated into a standard hygiene item with an analysis device 4 located in it. The insert 2 is formed from a fluid-impermeable film which, when the insert 2 is introduced into a hygiene item or into the upper side of an absorbent element of a hygiene item, forms a separating means 8, which separates the analysis device 4 from the absorbent element materials of the hygiene item and prevents bodily fluids, specifically urine, which initially pass from a user of the hygiene item into the absorbent element of the hygiene item, from being able to reach the analysis device 4 from the absorbent element. Absorbent element materials in modern hygiene items contain ingredients, for example, superabsorbent polymer materials, which give off substances into the bodily fluid and thereby change its composition, particularly when measuring the pH, nitrite, leukocyte, glucose or electrolyte values. The reading determined in the analysis device would thus be falsified.

[0019] It is therefore proposed with the invention that the analysis device be divided or separated from the absorbent element materials in the hygiene item by means of the separating means 8. As already mentioned, the insert 2 is used for this purpose. The insert 2 has sidewalls 10 extending up on the body side of a user. Edges 12 of the insert 2, which connect to the sidewalls 10, are folded over to the inside on one top side 14. The edges 12 are fixed in this position, specifically by means of an adhesive or welded joint 16, which is only suggested in Figures 1 and 3.

[0020] The insert 2 comprises, in addition to the analysis device 4, an absorption and transfer layer 18 to absorb and transfer bodily fluid which has been passed directly by a user of the hygiene item. This layer 18 is advantageously formed from a material which has adequate holding capacity to retain the bodily fluid and at the same time possesses sufficient capillary action to ensure that bodily fluid is transported within the layer 18, and in so doing without releasing substances which can have an influence on the result of the measurement to be made in the analysis device 4. Cellular materials are used advantageously, that is, preferably air-layered natural cellulose, but a viscose mat reinforced with bi-component fibers, for instance polyethylene, polypropylene, would be conceivable and advantageous.

- [0021] The storage layer 18 is used for absorbing and transferring the bodily fluid to the analysis device 4, and it also ensures that an adequate quantity of the bodily fluid to be analyzed is captured and kept in temporary storage.
- [0022] As can be seen from Figure 3, the analysis device 4 is positioned against one inner side 20 of the fluid-impermeable film 6 which forms the separating means 8. The film 6 is transparent in this area, so that it is possible to examine the analysis device 4 from the underside 22 of the insert 2. In order to take a reading from the analysis device 4, it has a visual display unit 24, which is visible through the transparent area 26 which forms a type of viewing window. The display unit 24 advantageously comprises colored indicators which undergo and display a color reaction corresponding to the concentration of a substance to be ascertained, which then by assignment to predetermined color panels enable the user of the analysis device 4 to evaluate the reading.
- [0023] The insert 2 is advantageously let into the upper side of an absorbent element of a hygiene item. After the hygiene item has been used, the entire insert 2 is detached from the hygiene item, which can then be thrown away. The insert 2 can then be conveniently folded together, where the film 6 forming the separating means 8 forms the outer side. By means of the aforementioned transparent area 26 it is possible to take a look at or read the display unit 24 of the analysis device 4.
- [0024] In order to fasten the insert 2 detachably to the hygiene item, the latter has touch-sensitive or adhesive means of attachment 28 on the side facing away from the body in use which, in the instance shown, for example, is supplied as strips extending along the entire longitudinal length of the insert 2.
- [0025] Figure 4 shows an insert 2 constructed corresponding to Figures 1 to 3, which differs from those described previously in that it has no dish-shaped edges extending up and turned over to the inside, but the separating means 8 delimiting the insert 2 is formed as a basically flat film 6. This insert 2 for the hygiene item, which is not shown, is therefore preferably applied to an upper side of the absorbent element of the hygiene item facing the body and detachably fastened there.

What is claimed is:

- 1 1. Single-use hygiene item, such as a diaper, incontinence article,
2 sanitary napkin, having an absorbent element for absorbing and retaining bodily fluid
3 and having an analysis device for the bodily fluid, characterized in that the analysis
4 device (4) is disposed at an area of the hygiene item on which the bodily fluid to be
5 analyzed can impinge and is separated in an essentially fluid-tight manner from the
6 absorbent element by a separating means (8), so that bodily fluid passed by a user to
7 be analyzed can reach the analysis device (4) directly, but bodily fluid that has
8 penetrated to the absorbent element is retained by the separating means (8) and kept
9 away from the analysis device (4).
- 1 2. Hygiene item in accordance with claim 1, wherein the
2 separating medium (8) forms an insert (2) in the absorbent element containing the
3 analysis device (4).
- 1 3. Hygiene item in accordance with claim 2, wherein the insert (2)
2 is dish-shaped.
- 1 4. Hygiene item in accordance with claim 2 or 3, wherein the
2 insert (2) has sidewalls (10) extending up on the side facing the body.
- 1 5. Hygiene item in accordance with one of the preceding claims 2
2 to 4, wherein edges (12) of the insert (2) are folded over on their upper side (14).
- 1 6. Hygiene item in accordance with one of the preceding claims 2
2 to 5, wherein the insert (2) delineated by a fluid-impermeable film (6).
- 1 7. Hygiene item in accordance with one of the preceding claims,
2 wherein the insert (2) is located essentially flush-mounted with the upper side (14) of
3 the absorbent element facing the body.

1 8. Hygiene item in accordance with one of the preceding claims,
2 wherein the analysis device (4) is positioned up against one side (20) of the
3 separating means (8).

1 9. Hygiene item in accordance with one of the preceding claims,
2 wherein the analysis device (4) has a visual display unit.

1 10. Hygiene item in accordance with claim 8 or 9, wherein the side
2 (20) of the separating means (8) against which the analysis device is lying, is made
3 transparent, at least in the area of the analysis device (4), so that a visual reading of
4 the display unit is possible.

1 11. Hygiene item in accordance with one of the preceding claims,
2 wherein the separating means (8) containing the analysis device is separable from the
3 hygiene item.

1 12. Hygiene item in accordance with one of the preceding claims,
2 wherein the separating means (8) containing the analysis device (4) is fastened
3 detachably to the hygiene item by means of adhesive or touch-sensitive means of
4 attachment (28).

1 13. Hygiene item in accordance with one of the preceding claims,
2 wherein the insert (2) containing the analysis device has a fluid absorbing and
3 transport layer (18) which transfers the bodily fluid to the analysis device.

1 14. Hygiene item in accordance with claim 13, wherein the fluid
2 absorbing and transport layer (18) comprises cellulose fibers without the addition of
3 superabsorbent polymer materials.

1 15. Use of an analysis device for measuring the composition of
2 bodily fluids, specifically for measuring pH, nitrite, leukocyte, glucose and/or

- 3 electrolyte values of urine or blood, in a single-use hygiene item having an absorbent
4 element to absorb and retain bodily fluids, such as a diaper, incontinence article or
5 sanitary napkin.

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JCO9 Rec'd PGT/PTO 27 SEP 2001

SINGLE-USE HYGIENE ITEMS

[Title: Single-Use Hygiene Items]

BACKGROUND
[Description]

5 The invention relates to a single-use hygiene item, such as a diaper, an incontinence article or a sanitary napkin, having an absorbent element for absorbing and retaining bodily fluids and having an analysis device for the bodily fluid.

Hygiene items are known which have indicator strips which undergo a change in color when wetted with urine and thus indicate in a visually perceptible manner when they are saturated. Since these indicator strips, in the broadest sense, represent an analysis device for the bodily fluid, the point of departure [in the characterizing portion] for the present invention was a hygiene item having an analysis device.

However, in the case of hygiene items, there is not only the necessity of monitoring their state of saturation and of indicating when the hygiene item is in a depleted condition, there is the fundamental need to analyze urine, for example, with respect to its composition. Consequently, the proposal is put forward in EP 0 438 482 B1 to provide an analysis device in a urine collection bag with indicating devices exposed to urine. Specifically, they are indicating devices which analyze the urine reaching the urine collection bag for its pH, nitrite, leukocyte, glucose and electrolyte values. The indicating devices are initially white and change color after being wetted with the urine to be analyzed. In an acidic medium, for example, a section of a pH-value indicator will turn yellow and in an alkaline medium it will turn blue. Analysis devices, identified as control cards, are described, having a color chart with several colors under a particular indicator section, by means of which a user can assign the color reaction of the indicator being monitored to a value. This value is given in another line below the color chart.

According to the teaching of this publication, each particular indicator panel on the urine-exposed side is covered by a membrane which has perforations consisting of extremely small holes. This membrane forms a type of metering device and allows the urine to reach the indicator panel only very slowly. In this way an initial flow of urine entering the empty collection bag with a high concentration of germs is prevented from causing a supercritical display which cannot normally be triggered by the main urine stream. In the same way, the residual urine, which differs

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from the main stream, also cannot determine the reading by itself. As a result of the relatively slowed down passage through the membrane, the urine to be analyzed is brought to the indicator panel "well mixed." In an advantageous further configuration of the analysis device, this publication describes that the indicator substances of the indicator field are embedded in a material which swells in the presence of moisture. In this way, as the material swells, pressure is built up against the membrane, and as a result the passage of urine is rendered even more difficult. In this way, flushing out of the color-creating indicator substances is counteracted, and an unbiased, accurate reading of the quasi-frozen display values can be taken even after many hours.

Whenever analysis devices are used, an effort is made, or a need even exists, to ensure that the substances to be analyzed come into contact in as unadulterated a form as possible with the measurement-sensitive means, that is to say, with the indicators on the analysis device, to ensure as accurate a measurement result as possible, free of any interaction.

For this reason the analysis device in accordance with the aforementioned EP 043842 B1 was also located in a urine routing system connected to a urethral catheter in the form of a urine collection bag.

This is naturally experienced as unpleasant by patients whose bodily fluid is to be subjected to analysis. In addition, it is a medically complicated procedure. In the case of incontinent persons, the possibility also does not exist of passing the bodily fluid to be analyzed into a container for purposes of analysis. Using this as the starting point, it would be desirable the object of the present invention is to expand the application of an intrinsically familiar analysis device described in EP 0 438 482 B1, specifically to render the use of a urine routing system attached to a urethral catheter unnecessary.

SUMMARY
design
This object is fulfilled through the use of an analysis device in accordance with the invention for measuring the composition of the bodily fluids, specifically for measuring pH, nitrite, leukocyte, glucose and/or electrolyte values of urine or blood, in a single-use hygiene item with an absorbent element for absorbing and retaining bodily fluids, as for example, a diaper, an incontinence article or a sanitary napkin [claim 15].

As a result of the use in accordance with the invention, it becomes possible for the first time to employ analysis devices for measuring the composition of bodily fluids outside a urine routing system. With the invention, protection is therefore also ^{provided} being claimed for an intrinsically familiar hygiene item which has an analysis device for measuring the composition of the bodily fluid to be absorbed, specifically for measuring pH, nitrite, leukocyte, glucose and/or electrolyte values.

In a further development of this concept, a hygiene item of the type described at the outset is proposed, which, in accordance with the invention, is characterized in that the analysis device is disposed at a place on the hygiene item which can be impinged upon by the bodily fluid to be analyzed and is separated by means of a separating means in an essentially fluid-tight manner from the absorbent element, so that bodily fluid passed by a user to be analyzed can reach the analysis device directly, but bodily fluid passed into the absorbent element is retained by the separating means and kept away from the analysis device (claim 1).

The ^{aspect}embodiment of the hygiene item according to the invention has the advantage that bodily fluid to be analyzed is not affected by interaction with absorbent element materials in the hygiene article which may be present and/or by the leaching out of substances from the absorbent element material which affect the analysis reaction, and thus falsify the result of the measurement. For example, the absorbent element of modern hygiene items normally comprises so-called superabsorbent polymer materials, which retain many times their own weight in fluid. These substances, however, have a falsifying effect on the measurement of individual components. Due to the fact that the analysis device is separated by the aforementioned separating means in a basically fluid-tight manner from the absorbent element of the hygiene item, it is ensured that urine which was biased as a result of the interaction with the materials of the absorbent element with respect to the analysis reaction, does not reach the analysis device and is not analyzed there.

The separating means could, in the simplest instance, comprise an essentially fluid-impermeable layer of film. The separating means in a further development of the invention forms an insert in the hygiene item containing the analysis device and/or in the absorbent element of the hygiene item. The term

"insert" is to be understood as an area of the hygiene item separated by the separating means from the remainder of the absorbent element. This insert or area can, for example, be dish-shaped and have side walls extending up on the side facing the body.

5

^{In aspect}
[Under a further embodiment] of the hygiene item according to the invention, edges of this insert are folded over on its top side.

The insert is advantageously delineated by a fluid-impermeable film, which simultaneously forms the separating means.

10

The separating means and/or the insert could be disposed as a relatively shallow elevation on the upper side of the absorbent element of the hygiene item, so that the insert is impinged upon first by the bodily fluid passed by a user of the hygiene item, which can then penetrate into the adjacent areas of the absorbent element after the insert is filled.

15

^{In aspect}
[Under a further advantageous embodiment] of the invention, the insert is located essentially flush over its surface with the top side of the absorbent element facing the body.

20

In essence, the analysis device could be disposed in any way at all, separated by the separating means from the absorbent element. In a further development of the invention, however, it is proposed that the analysis device is disposed resting against one side of the separating means. When the hygiene item is impinged upon by bodily fluid, the latter will normally travel as far as the separating means following gravity and there come into contact with the analysis device.

25

~~DETAILED DESCRIPTION~~
A standard, familiar hygiene item, for example, a diaper, an incontinence article or a sanitary napkin, can be made in accordance with the present invention, having an analysis device to measure and check the composition of bodily fluids. Figures 1 to 3 provide an initial embodiment of an insert 2 which can be integrated into a standard hygiene item with an analysis device 4 located in it. The insert 2 is formed from a fluid-impermeable film, which when the insert 2 is introduced into a hygiene item or into the upper side of an absorbent element of a hygiene item, forms a separating means 8, which separates the analysis device 4 from the absorbent element materials of the hygiene item and prevents bodily fluids,

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specifically urine, which initially pass from a user of the hygiene item into the absorbent element of the hygiene item, from being able to reach the analysis device 4 from ~~there~~ ^{the absorbent element}. Absorbent element materials in modern hygiene items contain ingredients, for example, superabsorbent polymer materials, which give off substances into the bodily fluid and thereby change its composition, particularly when measuring the pH, nitrite, leukocyte, glucose or electrolyte values. The reading determined in the analysis device would be falsified.

It is therefore proposed with the invention that the analysis device be divided or separated from the absorbent element materials in the hygiene item by means of the separating means 8. As already mentioned, the insert 2 is used for this purpose. The insert 2 has sidewalls 10 extending up on the body side of a user. Edges 12 of the insert 2, which connect to the sidewalls 10, are folded over to the inside on one top side 14. The edges 12 are fixed in this position, specifically by means of an adhesive or welded joint 16, which is only suggested in Figures 1 and 3.

The insert 2 comprises, in addition to the analysis device 4, an absorption and transfer layer 18 to absorb and transfer bodily fluid which has been passed directly by a user of the hygiene item. This layer 18 is advantageously formed from a material which has adequate holding capacity to retain the bodily fluid and at the same time possesses sufficient capillary action to ensure that bodily fluid is transported within the layer 18, and in so doing without releasing substances which can have an influence on the result of the measurement to be made in the analysis device 4. Cellular materials are used advantageously, that is, preferably air-layered natural cellulose, but a viscose mat reinforced with bi-component fibers, for instance polyethylene, polypropylene, would be conceivable and advantageous.

The storage layer 18 is used for absorbing and transferring the bodily fluid to the analysis device 4, ^{and} it also ensures that an adequate quantity of the bodily fluid to be analyzed is captured and kept in temporary storage.

As can be seen from Figure 3, the analysis device 4 is positioned against one inner side 20 of the fluid-impermeable film 6 which forms the separating means 8. The film 6 is transparent in this area, so that it is possible to examine the analysis device 4 from the underside 22 of the insert 2. In order to take a reading

from the analysis device 4, it has a visual display unit 24, which is visible through the transparent area 26 which forms a type of viewing window. The display unit 24 advantageously comprises colored indicators which undergo and display a color reaction corresponding to the concentration of a substance to be ascertained, which then by assignment to predetermined color panels enable the user of the analysis device 4 to evaluate the reading.

The insert 2 is advantageously let into the upper side of an absorbent element of a hygiene item. After the hygiene item has been used, the entire insert 2 is detached from the hygiene item, which can then be thrown away. The insert 2 can then be conveniently folded together, where the film 6 forming the separating means 8 forms the outer side. By means of the aforementioned transparent area 26 it is possible to take a look at or read the display unit 24 of the analysis device 4.

In order to fasten the insert 2 detachably to the hygiene item, the latter has touch-sensitive or adhesive means of attachment 28 on the side facing away from the body in use, which, in the instance shown, for example, ^{is} supplied as strips extending ^{along} the entire longitudinal length of the insert 2.

Figure 4 shows an insert 2 constructed corresponding to Figures 1 to 3, which differs from those described previously in that it has no dish-shaped edges extending up and turned over to the inside, but the separating means 8 delimiting the insert 2 is formed as a basically flat film 6. This insert 2 for the hygiene item, which is not shown, is therefore preferably applied to an upper side of the absorbent element of the hygiene item facing the body and fastened there detachably.

detachably

What is claimed is:

{ What Is Claimed Is: }

1. Single-use hygiene item, such as a diaper, incontinence article, sanitary napkin, having an absorbent element for absorbing and retaining bodily fluid and having an analysis device for the bodily fluid, characterized in that the analysis device (4) is disposed at an area of the hygiene item on which the bodily fluid to be analyzed can impinge and is separated in an essentially fluid-tight manner from the absorbent element by a separating means (8), so that bodily fluid passed by a user to be analyzed can reach the analysis device (4) directly, but bodily fluid that has penetrated to the absorbent element is retained by the separating means (8) and kept away from the analysis device (4).
2. Hygiene item in accordance with claim 1, wherein the separating medium (8) forms an insert (2) in the absorbent element containing the analysis device (4).
3. Hygiene item in accordance with claim 2, wherein the insert (2) is dish-shaped.
4. Hygiene item in accordance with claim 2 or 3, wherein the insert (2) has sidewalls (10) extending up on the side facing the body.
5. Hygiene item in accordance with one of the preceding claims 2 to 4, wherein edges (12) of the insert (2) are folded over on their upper side (14).
6. Hygiene item in accordance with one of the preceding claims 2 to 5, wherein the insert (2) delineated by a fluid-impermeable film (6).
7. Hygiene item in accordance with one of the preceding claims, wherein the insert (2) is located essentially flush-mounted with the upper side (14) of the absorbent element facing the body.

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8. Hygiene item in accordance with one of the preceding claims, wherein the analysis device (4) is positioned up against one side (20) of the separating means (8).

5 9. Hygiene item in accordance with one of the preceding claims, wherein the analysis device (4) has a visual display unit.

10 10. Hygiene item in accordance with claim 8 or 9, wherein the side (20) of the separating means (8) against which the analysis device is lying, is made transparent, at least in the area of the analysis device (4), so that a visual reading of the display unit is possible.

10 11. Hygiene item in accordance with one of the preceding claims, wherein the separating means (8) containing the analysis device is separable from the hygiene item.

15 12. Hygiene item in accordance with one of the preceding claims, wherein the separating means (8) containing the analysis device (4) is fastened detachably to the hygiene item by means of adhesive or touch-sensitive means of attachment (28).

13. Hygiene item in accordance with one of the preceding claims, wherein the insert (2) containing the analysis device has a fluid absorbing and transport layer (18) which transfers the bodily fluid to the analysis device.

20 14. Hygiene item in accordance with claim 13, wherein the fluid absorbing and transport layer (18) comprises cellulose fibers without the addition of superabsorbent polymer materials.

15. Use of an analysis device for measuring the composition of bodily fluids, specifically for measuring pH, nitrite, leukocyte, glucose and/or

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electrolyte values of urine or blood, in a single-use hygiene item having an absorbent element to absorb and retain bodily fluids, such as a diaper, incontinence article or sanitary napkin.

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Title: Single-Use Hygiene Items

Description

The invention relates to a single-use hygiene item, such as a diaper, an incontinence article or a sanitary napkin, having an absorbent element for absorbing and retaining bodily fluids and having an analysis device for the bodily fluid.

Hygiene items are known which have indicator strips which undergo a change in color when wetted with urine and thus indicate in a visually perceptible manner when they are saturated. Since these indicator strips, in the broadest sense, represent an analysis device for the bodily fluid, the point of departure in the characterizing portion was a hygiene item having an analysis device.

However, in the case of hygiene items there is not only the necessity of monitoring their state of saturation and of indicating when the hygiene item is in a depleted condition, there is the fundamental need to analyze urine, for example, with respect to its composition. Consequently, the proposal is put forward in EP 0 438 482 B1 to provide an analysis device in a urine collection bag with indicating devices exposed to urine. Specifically, they are indicating devices which analyze the urine reaching the urine collection bag for its pH, nitrite, leukocyte, glucose and electrolyte values. The indicating devices are initially white and change color after being wetted with the urine to be analyzed. In an acidic medium, for example, a section of a pH-value indicator will turn yellow and in an alkaline medium it will turn blue. Analysis devices, identified as control cards, are described, having a color chart with several colors under a particular indicator section, by means of which a user can assign the color reaction of the indicator being monitored to a value. This value is given in another line below the color chart.

According to the teaching of this publication, each particular indicator panel on the urine-exposed side is covered by a membrane which has perforations consisting of extremely small holes. This membrane forms a type of metering device and allows the urine to reach the indicator panel only very slowly. In this way an initial flow of urine entering the empty collection bag with a high concentration of germs is prevented from causing a supercritical display which cannot normally be triggered by the main urine stream. In the same way, the residual urine, which differs

from the main stream, also cannot determine the reading by itself. As a result of the relatively slowed down passage through the membrane, the urine to be analyzed is brought to the indicator panel "well mixed." In an advantageous further configuration of the analysis device, this publication describes that the indicator substances of the indicator field are embedded in a material which swells in the presence of moisture. In this way, as the material swells, pressure is built up against the membrane, and as a result the passage of urine is rendered even more difficult. In this way, flushing out of the color-creating indicator substances is counteracted, and an unbiased, accurate reading of the quasi-frozen display values can be taken even after many hours.

Whenever analysis devices are used, an effort is made, or a need even exists, to ensure that the substances to be analyzed come into contact in as unadulterated a form as possible with the measurement-sensitive means, that is to say with the indicators on the analysis device, to ensure as accurate a measurement result as possible, free of any interaction.

For this reason the analysis device in accordance with the aforementioned EP 043842 B1 was also located in a urine routing system connected to a urethral catheter in the form of a urine collection bag.

This is naturally experienced as unpleasant by patients whose bodily fluid is to be subjected to analysis. In addition, it is a medically complicated procedure. In the case of incontinent persons the possibility also does not exist of passing the bodily fluid to be analyzed into a container for purposes of analysis. Using this as the starting point, the object of the present invention is to expand the application of an intrinsically familiar analysis device described in EP 0 438 482 B1, specifically to render the use of a urine routing system attached to a urethral catheter unnecessary.

This object is fulfilled through the use of an analysis device in accordance with the invention for measuring the composition of the bodily fluids, specifically for measuring pH, nitrite, leukocyte, glucose and/or electrolyte values of urine or blood, in a single-use hygiene item with an absorbent element for absorbing and retaining bodily fluids, as for example, a diaper, an incontinence article or a sanitary napkin (claim 15).

As a result of the use in accordance with the invention it becomes possible for the first time to employ analysis devices for measuring the composition of bodily fluids outside a urine routing system. With the invention, protection is therefore also being claimed for an intrinsically familiar hygiene item which has an analysis device for measuring the composition of the bodily fluid to be absorbed, specifically for measuring pH, nitrite, leukocyte, glucose and/or electrolyte values.

In a further development of this concept, a hygiene item of the type described at the outset is proposed, which, in accordance with the invention, is characterized in that the analysis device is disposed at a place on the hygiene item which can be impinged upon by the bodily fluid to be analyzed and is separated by means of a separating means in an essentially fluid-tight manner from the absorbent element, so that bodily fluid passed by a user to be analyzed can reach the analysis device directly, but bodily fluid passed into the absorbent element is retained by the separating means and kept away from the analysis device (claim 1).

The embodiment of the hygiene item according to the invention has the advantage that bodily fluid to be analyzed is not affected by interaction with absorbent element materials in the hygiene article which may be present and/or by the leaching out of substances from the absorbent element material which affect the analysis reaction, and thus falsify the result of the measurement. For example, the absorbent element of modern hygiene items normally comprises so-called superabsorbent polymer materials, which retain many times their own weight in fluid. These substances, however, have a falsifying effect on the measurement of individual components. Due to the fact that the analysis device is separated by the aforementioned separating means in a basically fluid-tight manner from the absorbent element of the hygiene item, it is ensured that urine which was biased as a result of the interaction with the materials of the absorbent element with respect to the analysis reaction, does not reach the analysis device and is not analyzed there.

The separating means could, in the simplest instance, comprise an essentially fluid-impermeable layer of film. The separating means in a further development of the invention forms an insert in the hygiene item containing the analysis device and/or in the absorbent element of the hygiene item. The term

"insert" is to be understood as an area of the hygiene item separated by the separating means from the remainder of the absorbent element. This insert or area can, for example, be dish-shaped and have side walls extending up on the side facing the body.

5 Under a further embodiment of the hygiene item according to the invention, edges of this insert are folded over on its top side.

The insert is advantageously delineated by a fluid-impermeable film, which simultaneously forms the separating means.

10 The separating means and/or the insert could be disposed as a relatively shallow elevation on the upper side of the absorbent element of the hygiene item, so that the insert is impinged upon first by the bodily fluid passed by a user of the hygiene item, which can then penetrate into the adjacent areas of the absorbent element after the insert is filled.

15 Under a further advantageous embodiment of the invention, the insert is located essentially flush over its surface with the top side of the absorbent element facing the body.

In essence, the analysis device could be disposed in any way at all, separated by the separating means from the absorbent element. In a further development of the invention, however, it is proposed that the analysis device is
20 disposed resting against one side of the separating means. When the hygiene item is impinged upon by bodily fluid, the latter will normally travel as far as the separating means following gravity and there come into contact with the analysis device.

A standard, familiar hygiene item, for example, a diaper, an incontinence article or a sanitary napkin, can be made in accordance with the present
25 invention, having an analysis device to measure and check the composition of bodily fluids. Figures 1 to 3 provide an initial embodiment of an insert 2 which can be integrated into a standard hygiene item with an analysis device 4 located in it. The insert 2 is formed from a fluid-impermeable film, which when the insert 2 is introduced into a hygiene item or into the upper side of an absorbent element of a
30 hygiene item, forms a separating means 8, which separates the analysis device 4 from the absorbent element materials of the hygiene item and prevents bodily fluids,

specifically urine, which initially pass from a user of the hygiene item into the absorbent element of the hygiene item, from being able to reach the analysis device 4 from there. Absorbent element materials in modern hygiene items contain ingredients, for example, superabsorbent polymer materials which give off substances into the bodily fluid and thereby change its composition, particularly when measuring the pH, nitrite, leukocyte, glucose or electrolyte values. The reading determined in the analysis device would be falsified.

It is therefore proposed with the invention that the analysis device be divided or separated from the absorbent element materials in the hygiene item by means of the separating means 8. As already mentioned, the insert 2 is used for this purpose. The insert 2 has sidewalls 10 extending up on the body side of a user. Edges 12 of the insert 2, which connect to the sidewalls 10, are folded over to the inside on one top side 14. The edges 12 are fixed in this position, specifically by means of an adhesive or welded joint 16, which is only suggested in Figures 1 and 3.

The insert 2 comprises, in addition to the analysis device 4, an absorption and transfer layer 18 to absorb and transfer bodily fluid which has been passed directly by a user of the hygiene item. This layer 18 is advantageously formed from a material which has adequate holding capacity to retain the bodily fluid and at the same time possesses sufficient capillary action to ensure that bodily fluid is transported within the layer 18, and in so doing without releasing substances which can have an influence on the result of the measurement to be made in the analysis device 4. Cellular materials are used advantageously, that is, preferably air-layered natural cellulose, but a viscose mat reinforced with bi-component fibers, for instance polyethylene, polypropylene, would be conceivable and advantageous.

The storage layer 18 is used for absorbing and transferring the bodily fluid to the analysis device 4, it also ensures that an adequate quantity of the bodily fluid to be analyzed is captured and kept in temporary storage.

As can be seen from Figure 3, the analysis device 4 is positioned against one inner side 20 of the fluid-impermeable film 6 which forms the separating means 8. The film 6 is transparent in this area, so that it is possible to examine the analysis device 4 from the underside 22 of the insert 2. In order to take a reading

from the analysis device 4, it has a visual display unit 24, which is visible through the transparent area 26 which forms a type of viewing window. The display unit 24 advantageously comprises colored indicators which undergo and display a color reaction corresponding to the concentration of a substance to be ascertained, which then by assignment to predetermined color panels enable the user of the analysis device 4 to evaluate the reading.

The insert 2 is advantageously let into the upper side of an absorbent element of a hygiene item. After the hygiene item has been used, the entire insert 2 is detached from the hygiene item, which can then be thrown away. The insert 2 can then be conveniently folded together, where the film 6 forming the separating means 8 forms the outer side. By means of the aforementioned transparent area 26 it is possible to take a look at or read the display unit 24 of the analysis device 4.

In order to fasten the insert 2 detachably to the hygiene item, the latter has touch-sensitive or adhesive means of attachment 28 on the side facing away from the body in use, which in the instance shown, for example, are supplied as strips extending the entire longitudinal length of the insert 2.

Figure 4 shows an insert 2 constructed corresponding to Figures 1 to 3, which differs from those described previously in that it has no dish-shaped edges extending up and turned over to the inside, but the separating means 8 delimiting the insert 2 is formed as a basically flat film 6. This insert 2 for the hygiene item, which is not shown, is therefore preferably applied to an upper side of the absorbent element of the hygiene item facing the body and fastened there detachably.

What Is Claimed Is:

1. Single-use hygiene item, such as a diaper, incontinence article, sanitary napkin, having an absorbent element for absorbing and retaining bodily fluid and having an analysis device for the bodily fluid, characterized in that the analysis device (4) is disposed at an area of the hygiene item on which the bodily fluid to be analyzed can impinge and is separated in an essentially fluid-tight manner from the absorbent element by a separating means (8), so that bodily fluid passed by a user to be analyzed can reach the analysis device (4) directly, but bodily fluid that has penetrated to the absorbent element is retained by the separating means (8) and kept away from the analysis device (4).
2. Hygiene item in accordance with claim 1, wherein the separating medium (8) forms an insert (2) in the absorbent element containing the analysis device (4).
3. Hygiene item in accordance with claim 2, wherein the insert (2) is dish-shaped.
4. Hygiene item in accordance with claim 2 or 3, wherein the insert (2) has sidewalls (10) extending up on the side facing the body.
5. Hygiene item in accordance with one of the preceding claims 2 to 4, wherein edges (12) of the insert (2) are folded over on their upper side (14).
6. Hygiene item in accordance with one of the preceding claims 2 to 5, wherein the insert (2) delineated by a fluid-impermeable film (6).
7. Hygiene item in accordance with one of the preceding claims, wherein the insert (2) is located essentially flush-mounted with the upper side (14) of the absorbent element facing the body.

8. Hygiene item in accordance with one of the preceding claims, wherein the analysis device (4) is positioned up against one side (20) of the separating means (8).

5 9. Hygiene item in accordance with one of the preceding claims, wherein the analysis device (4) has a visual display unit.

10. Hygiene item in accordance with claim 8 or 9, wherein the side (20) of the separating means (8) against which the analysis device is lying, is made transparent, at least in the area of the analysis device (4), so that a visual reading of the display unit is possible.

10 11. Hygiene item in accordance with one of the preceding claims, wherein the separating means (8) containing the analysis device is separable from the hygiene item.

15 12. Hygiene item in accordance with one of the preceding claims, wherein the separating means (8) containing the analysis device (4) is fastened detachably to the hygiene item by means of adhesive or touch-sensitive means of attachment (28).

13. Hygiene item in accordance with one of the preceding claims, wherein the insert (2) containing the analysis device has a fluid absorbing and transport layer (18) which transfers the bodily fluid to the analysis device.

20 14. Hygiene item in accordance with claim 13, wherein the fluid absorbing and transport layer (18) comprises cellulose fibers without the addition of superabsorbent polymer materials.

15. Use of an analysis device for measuring the composition of bodily fluids, specifically for measuring pH, nitrite, leukocyte, glucose and/or

electrolyte values of urine or blood, in a single-use hygiene item having an absorbent element to absorb and retain bodily fluids, such as a diaper, incontinence article or sanitary napkin.

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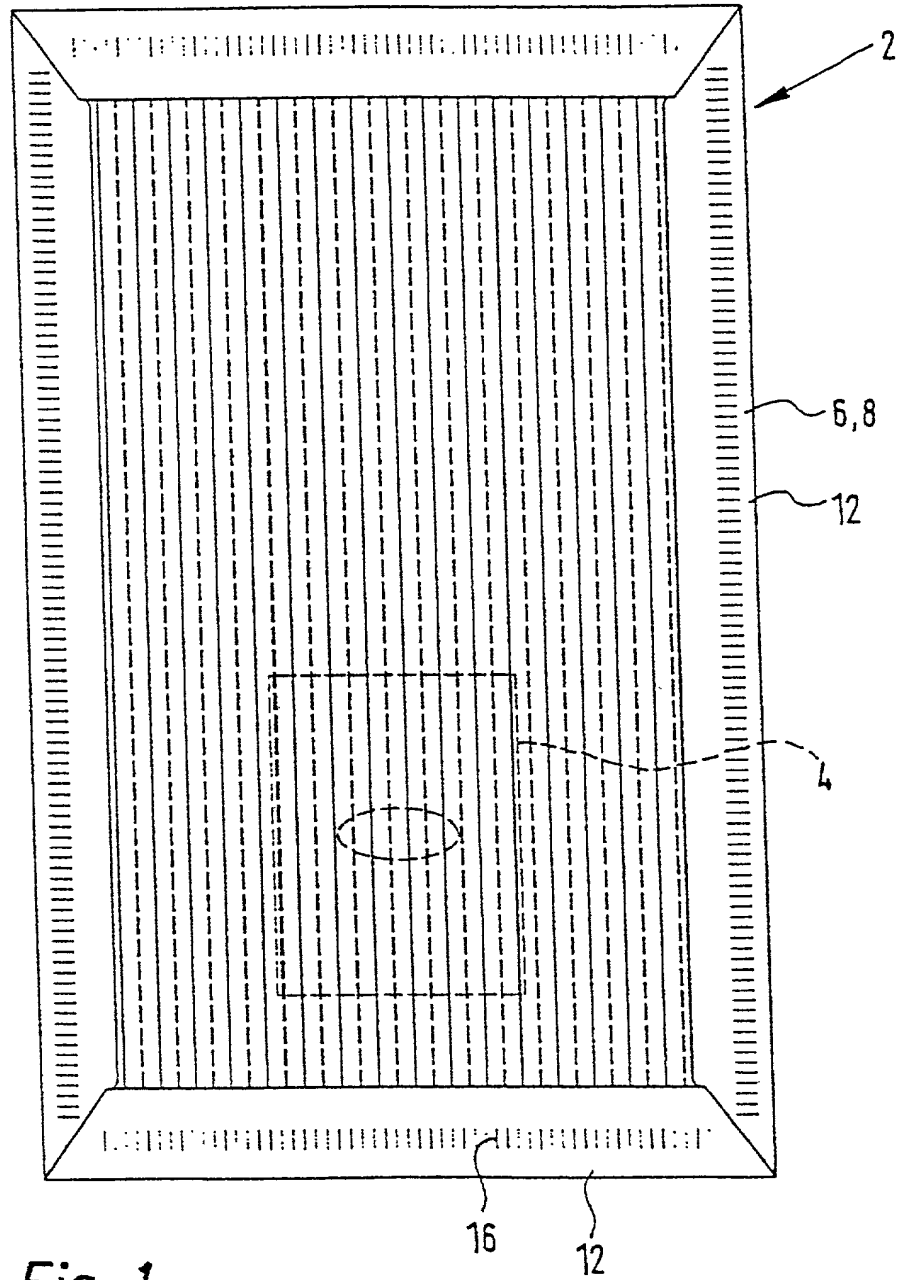


Fig. 1

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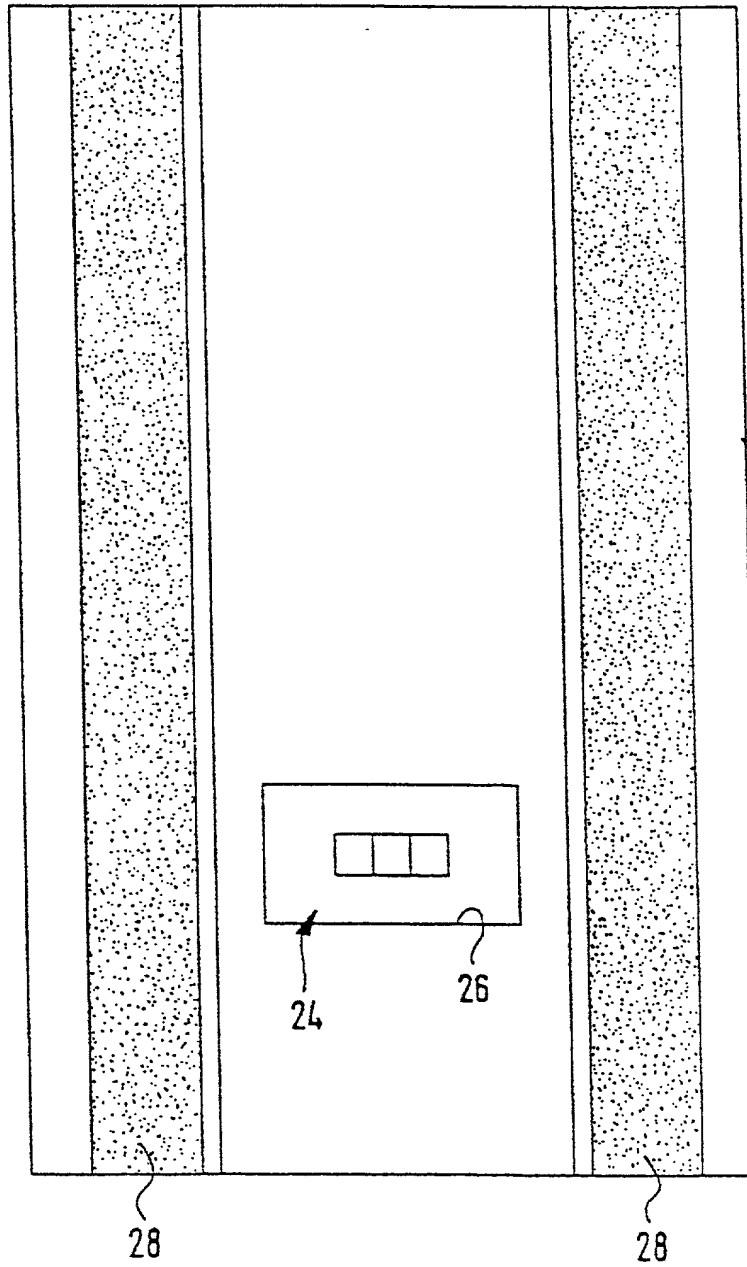
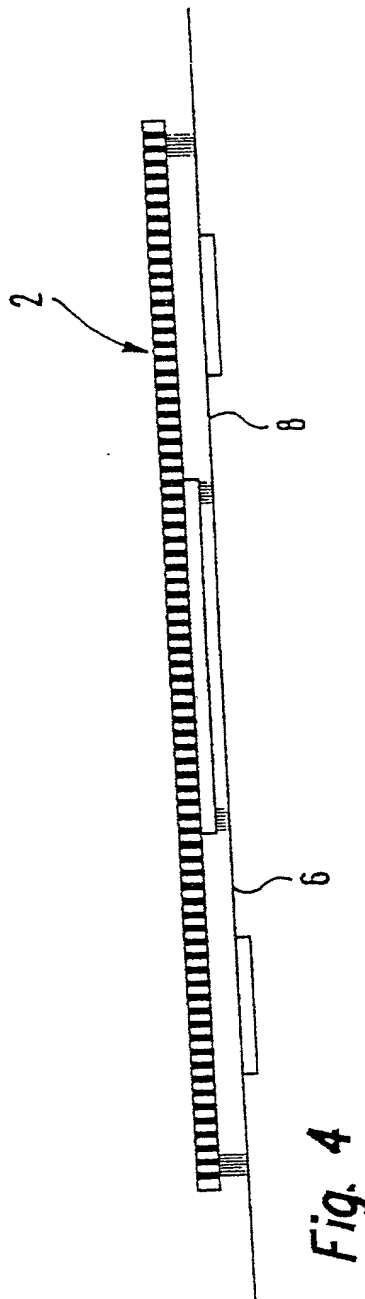
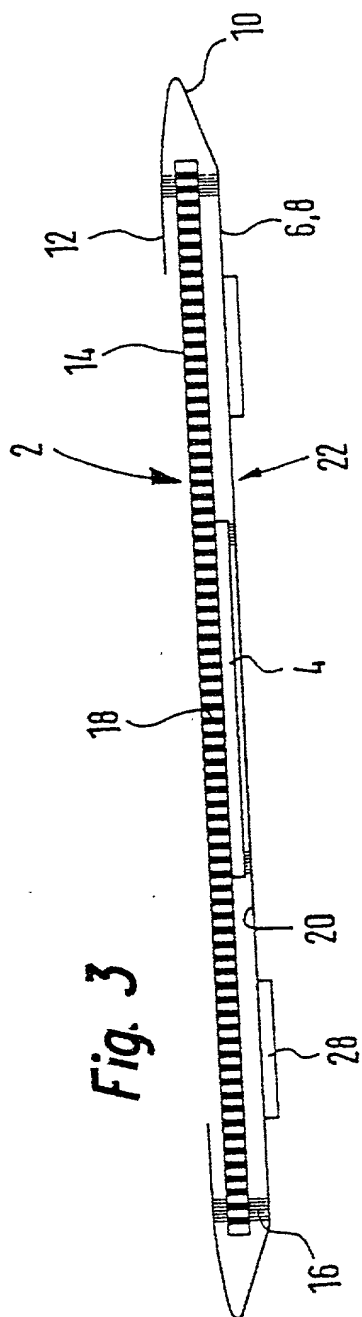


Fig. 2



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Our Reference: DFS-129-A

COMBINED DECLARATION AND POWER OF ATTORNEY

DECLARATION:

As a below named inventor, I hereby declare that:
My residence, post office address and citizenship are as stated below next to my name.
I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

SINGLE-USE HYGIENE ITEMS

the specification of which (check only one item below):

- ☐ is attached hereto.
- ☐ was filed as United States application Serial No. _____ on _____, and was amended on or through _____ (if applicable).
- ☒ was filed as PCT international application Number PCT/EP00/01824 on 03 March 2000, and was amended under PCT Article 19 on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, §1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, §119(a)-(d) or §365(b) of any foreign application(s) for patent or inventor's certificate or §365(a) of any PCT international application(s) which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or PCT international application(s) having a filing date before that of the application on which priority is claimed:

Prior Foreign/PCT Application(s) and any Priority Claims Under 35 U.S.C. §119:			Priority Claimed	
<u>199 14 037.5</u>	<u>Germany</u>	<u>27 March 1999</u>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
(Number)	(Country)	(Day/Mo/Yr Filed)	Yes	No
_____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>
(Number)	(Country)	(Day/Mo/Yr Filed)	Yes	No

I hereby claim the benefit under 35 U.S.C. §119(e) of any United States provisional application(s) listed below.

_____	_____
(Application Number)	(Filing Date)
_____	_____
(Application Number)	(Filing Date)

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) or §365(c) of any PCT international application(s) designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, §1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

Prior U. S. Application(s) or PCT International Application(s) Designating the U.S. for Benefit Under 35 U.S.C. §120:

_____	_____	_____
(Application Number)	(Filing Date)	(Status: patented, pending, abandoned)
_____	_____	_____
(Application Number)	(Filing Date)	(Status: patented, pending, abandoned)

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POWER OF ATTORNEY:

3 I hereby appoint the following attorney(s) and/or agent(s) William M. Hanlon, Jr., Patent Office Registration No. 28422, Andrew R. Basile, Patent Office Registration No. 24753, Thomas D. Helmholdt, Patent Office Registration No. 33181, as my attorney(s) and/or agent(s), to prosecute this application and to transact all business in the United States Patent and Trademark Office connected therewith.

Send all correspondence to: William M. Hanlon, Jr.
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3001 West Big Beaver Road, Suite 624
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Phone: (248) 649-3333

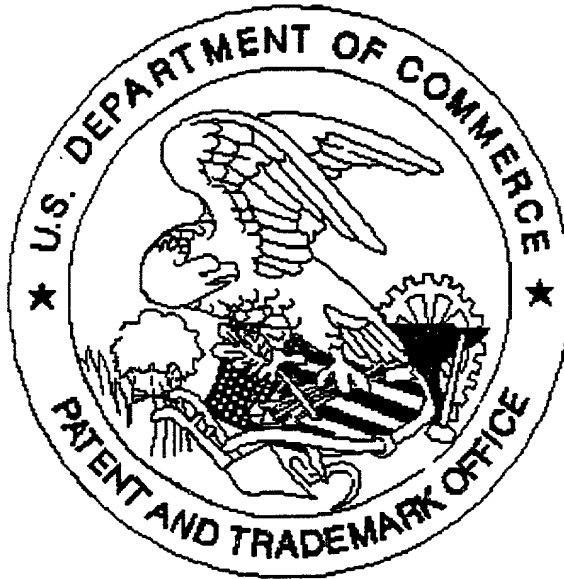
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor Andreas Bitterhof
Inventor's Signature [Signature]
Date 03/09/2001 Citizenship German
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